



10-15-03

#1636

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Dakai Liu and Elazar Rabbani

Serial No. 09/046,840

Group Art Unit: 1636

Filed: March 24, 1998

Examiner: David Guzo

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TECH CENTER 1600/2900

Title: VECTORS, VIRAL VECTORS AND PACKAGING CELL LINES FOR PROPAGATING SAME

TRANSMITTAL  
INFORMATION DISCLOSURE STATEMENT

HON. COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

Sir:

Transmitted herewith is an Information Disclosure Statement which is being filed in accordance with 37 C.F.R. §§ 1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

**EXPRESS MAIL CERTIFICATE**

"Express Mail" Label No.: EV 063168838

Deposit Date: October 14, 2003

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

  
Ronald C. Fedus  
Reg. Exhibit 32,567

OCT 14 2003  
Date

Enz-56(D3)

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior ☐ Divisional or ☐ Continuation-In-Part application under 37 C.F.R. §1.60, U.S. Serial No. \_\_\_\_\_, filed \_\_\_\_\_.
4. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
  - ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application.
  - ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application.
  - ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☒ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
  - ☐ A check in the amount of \$240.00 is enclosed in payment of the fee.

☒ Charge the fee to Deposit Account No. 05-1135, Order No. ENZ-56(D3). A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

7. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:

- a. one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
- b. the attached petition requesting consideration of this Information Disclosure Statement; and
- c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.

8. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:

- a. ☐ 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
- b. ☐ 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.
- c. ☐ The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.

9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

**Enz-56(D3)**

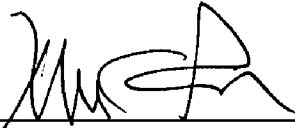
10. [ ] A check in the amount of \$130.00 is enclosed in payment of the fee due under 37 C.F.R. §1.17(i)(1).

[X] Charge the fee under 37 C.F.R. §1.17(i)(1) to Deposit Account No. 05-1135. Order No. ENZ-56(D3). A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

[x] The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 05-1135. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

Dated: October 14, 2003

By:   
RONALD C. FEDUS  
Registration No. 32,567

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**Enz-56(D3)**



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Serial No. 09/046,840 )  
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527 Madison Avenue, 9<sup>th</sup> Floor  
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October 14, 2003

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§1.56 & 1.97-1.98**

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.97-1.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following fifty-eight (58) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

10/21/2003 MROCHA1 00000007 051135 09046848

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Dakai Liu and Elazar Rabbani

Serial No.: 09/046,840

Filed: March 24, 1998

Page 2 [Information Disclosure Statement

-- October 14, 2003]

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\_\_\_\_\_  
Ronald C. Fedus  
Reg. Exhibit 32,567

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1. Morgenstern, J.P. et al, "Choice and Manipulation of Retroviral Vectors," Gene Transfer and Expression Protocols. Methods in Molecular Biology, Vol. 7:181-193; (1991), Murray, E.J., Ed., The Humana Press, New Jersey **[EXHIBIT 1]**
2. Anderson, W.F, "Human Gene Therapy," Science 256:808-813 (1992) **[EXHIBIT 2]**
3. Mulligan, R.C, "The Basic Science of Gene Therapy," Science 260:926-932 (1993) **[EXHIBIT 3]**
4. Smith, A.E, "Viral Vectors in Gene Therapy," Ann Rev. Microbiol, 49:807-38 (1995) **[EXHIBIT 4]**
5. Muzyczka, N, "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells," Current Topics in Microbiology and Immunology 158:97-129 (1992) **[EXHIBIT 5]**
6. Kotin, R.M, "Prospects for the Use of Adeno-Associated Virus as a Vector for Human Gene Therapy," Human Gene Therapy 5:793-801 (1994) **[EXHIBIT 6]**
7. Berkner, K.L, Curr. Top. Microbiol. Immunol. 158:39-66 (1992) **[EXHIBIT 7]**
8. Emerman, M et al., "Genes with Promoters in Retrovirus Vectors Can Be Independently Suppressed by an Epigenetic Mechanism," Cell 39:459-467 (1984) **[EXHIBIT 8]**
9. Emerman, M et al., "Quantitative Analysis of Gene Suppression in Integrated Retrovirus Vectors," Molecular and Cellular Biology 6(1):792-800 (1986) **[EXHIBIT 9]**
10. Emerman, M et al., Nucleic Acids Res. 14:9381-9396 (1986)**[EXHIBIT 10]**
11. Yu, S.F et al., "Self-inactivating retroviral vectors designed for transfer of whole genes into mammalian cells," Proc. Natl. Acad. Sci. USA 83:3194-3198 (1986) **[EXHIBIT 11]**

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12. Hawley, R.G. et al., "Handicapped retroviral vectors efficiently transduce foreign genes into hematopoietic stem cells," Proc. Natl. Acad. Sci. USA 84: 2406-2410 (1987) [EXHIBIT 12]
13. Yee, J.K et al., "Gene expression from transcriptionally disabled retroviral vectors," Proc. Natl. Acad. Sci. USA 84:5197-5201 (1987) [EXHIBIT 13]
14. Dougherty, J.P and Temin H.M., "A promoterless retroviral vector indicates that there are sequences in U3 required for 3' RNA processing," Proc. Natl. Acad. Sci. USA 84:1197-1201 (1987) [EXHIBIT 14]
15. Whitcomb, J.M and Hughes, S.H., "Retroviral Reverse Transcription and integration: Progress and Problems" Ann. Rev. Cell Biol. 8:275-306 (1992) [EXHIBIT 15]
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17. Fung, Y.T. et al., "On the mechanism of retrovirus-induced avian lymphoid leucosis: Deletion and integration of the proviruses," Proc. Natl. Acad. Sci. USA 78(6):3418-3422 (1981) [EXHIBIT 17]
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20. Lewin, B. Genes V; Oxford University Press, New York (1994) [EXHIBIT 20]
21. Samulski, R.J et al., "Targeted integration of adeno-associated virus (AAV) into human chromosome 19," The EMBO Journal 10(12):3941-3950 (1991) [EXHIBIT 21]
22. Kotin, R.M et al., "Mapping and Direct Visualization of a Region-Specific Viral DNA Integration Site on Chromosome 19q13-qter," Genomics 10:831-834 (1991) [EXHIBIT 22]



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24. Sambrook, J., Fritsch, E.F. and Maniatis, T. Molecular Cloning 2nd ed. Cold Spring Laboratory, Cold Spring Harbor, NY, 1989 [EXHIBIT 24]
25. Manser, T. and Gesteland R.F., "Human U1 Loci: Genes for Human U1 RNA Have Dramatically Similar Genomic Environments." Cell 29:257-264 (1982) [EXHIBIT 25]
26. Roy-Chowdhury et al., WO 98/37917 filed Feb. 26, 1998, with a priority date of February 28, 1997 based upon U.S. Patent Application Serial No. 08/808,629, now abandoned [EXHIBIT 26]
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32. Maddon, P.J et al., Cell 47:333-348 (1986) [EXHIBIT 32]
33. Lever, A.M.L, "Gene therapy for HIV infection," British Medical Bulletin, 51(1):149-166 (1995) [EXHIBIT 33]

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35. Wagner E. et al., "Coupling of adenovirus to transferring-polysine/DNA complexes greatly enhances receptor-mediated gene delivery and expression of transfected genes." Proc. Natl. Acad. Sci. USA 89: 6099-6103 (1992) [EXHIBIT 35]
36. Wu et al., U.S. Patent No. 5,166,320 [EXHIBIT 36]
37. Ruoslahti E. et al., "Alignment of Biologically Active Domains in the Fibronectin Molecule," The Journal of Biological Chemistry 256(14):7277-7281 (1981) [EXHIBIT 37]
38. Crisitiano R.J. et al., "Hepatic gene therapy: Adenovirus enhancement of receptor-mediated gene delivery and expression in primary hepatocytes," Proc Natl. Acad. Sci. USA 90:2122-2136 [EXHIBIT 38]
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42. Zieve, G.W and Sauterer R.A., "Cell Biology of the snRNP Particles," Biochemistry and Molecular Biology 25(1):1-46 (1990) [EXHIBIT 42]
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44. Sattentau, Q.J. and Weiss, R.A., "The CD4 Antigen: Physiological Ligand and HIV Receptor," Cell 52:631-633 (1988) [EXHIBIT 44]

45. Robinson, William S., "Hepadnaviridae and Their Replication," chapter in Field's Virology, Vol.2, edited by Fields, Bernard N., 2<sup>nd</sup> Edition, Ravens Press, pp. 2137-2169 (1990) [EXHIBIT 45]
46. Craigle, R. et al., Cell 62:829-837 (1990) [EXHIBIT 46]
47. Liu, D. et al., "Stable Human Immunodeficiency Virus Type 1 (HIV-1) Resistance in Transformed CD4<sup>+</sup> Monocytic Cells Treated with Multitargeting HIV-1 Antisense Sequences Incorporated into U1 snRNA," Journal of Virology 71(5):4079-4085 (1997) [EXHIBIT 47].
48. Wong-Stall et al., U.S. Patent No. 5,650,309 issued July 22, 1997 [EXHIBIT 48].
49. Kaleko, U.S. Patent No. 6,156,479 issued December 5, 2000 [EXHIBIT 49]
50. Wilson et al., U.S. Patent No. 5,856,152 issued January 5, 1999 [EXHIBIT 50].
51. Miller, et al., "Improved Retroviral Vectors for Gene Transfer and Expression," Biotechniques, Vol. 7(9):980-990 (1989) [EXHIBIT 51].
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53. Bank, et al., U.S. Patent Number 5,278,056 (1994) [EXHIBIT 53].
54. Van Den Wollenberg, D., et al, "Insertion of the human cytomegalovirus enhancer into a myeloproliferative sarcoma virus long terminal repeat creates a high-expression retroviral vector," Gene, Vol. 144(2):238-241 (1994) [EXHIBIT 54].
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57. Lund, A.H., et al, "Transcriptional silencing of retroviral vectors," Journal of

57. Lund, A.H., et al, "Transcriptional silencing of retroviral vectors," Journal of Biomedical Science, Vol. 3(6):365-378 (1996) [EXHIBIT 57].
58. Robinson, D., et al, "Retroviral vector with a CMV-IE/HIV-TAR hybrid LTR gives high basal expression levels and is up-regulated by HIV-1 TAT," Gene Therapy, Vol. 2(4):269-278 (1995) [EXHIBIT 58].

The first forty-seven (47) foregoing references (numbers 1-47) were cited in the specification of the instant application. Reference 48 was cited by the Examiner on Form PTO 892 in connection with an Office Action issued 09/28/99 in connection with the instant application. References 49 and 50 recently came to the attention of the instant application's assignee. References 51, 52 and 53 were cited in the International Search Report (PCT/US98/05725, dated July 14, 1998). References 54 through 58 were cited in the European Search Report (EP98915153, dated April 15, 2003).

A completed Form PTO-1449 listing the 58 above-submitted documents is also attached hereto as Exhibit 59.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the present application.


The above citation of documents is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant documents, nor are these documents necessarily a complete listing of all documents known to Applicants or their attorney. It is simply a voluntary citation of documents made in good faith, which is not intended to serve in any way as a substitute for the Examiner's own search.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither disclosed nor suggested by the documents referred to above and is thus patentably distinct thereover. Furthermore, Applicants do not believe, and do not submit, by the citation of these references, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under the duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant application.

The fee under 37 C.F.R. §1.17(p) for filing this Information Disclosure Statement is \$180.00. The Patent and Trademark Office is hereby authorized to charge the amount of this fee (and any other fees in connection with this IDS) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,



Ronald C. Fedus  
Registration No. 32,567  
Attorney for Applicants

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\* \* \* \* \*

Form PTO-1449 U.S. Department of Commerce

(REV. 8-83) Patent and Trademark Office

INFORMATION DISCLOSURE CITATION  
(use several sheets if necessary)Atty. Docket No.  
ENZ-56(D3)

Serial No. 09/046,840

Applicants: Dakai Liu and Elazar Rabbani

Filed: March 24, 1998

Group: 1636

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO- PRIATE
/D.G./	5 1 6 6 3 2 0	11-1992	Wu et al			
/D.G./	5 6 5 0 3 0 9	07-1997	Wong-Staal et al.			
/D.G./	5 2 7 8 0 5 6	01-1994	Bank et al.			
/D.G./	6 1 5 6 4 7 9	12-2000	Kaleko et al			
/D.G./	5 8 5 6 1 5 2	01-1999	Wilson et al			

## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN- SLATION YES NO
W O 9 8 3 7 9 1 7					
EP 0 1 2 8 3 3 2 B1					
EP 0 7 7 9 3 6 5 A2					

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Morgenstern, J.P. et al, "Choice and Manipulation of Retroviral Vectors," <u>Gene Transfer and Expression Protocols. Methods in Molecular Biology, Vol. 7:181-193; (1991),</u> Murray, E.J., Ed., The Humana Press, New Jersey
		Anderson, W.F, "Human Gene Therapy," <u>Science 256:808-813 (1992)</u>
		Mulligan, R.C, "The Basic Science of Gene Therapy," <u>Science 260:926-932(1993)</u>
		Smith, A.E, "Viral Vectors in Gene Therapy," <u>Ann Rev. Microbiol. 49:807-38(1995)</u>
		Muzyczka, N, "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells," <u>Current Topics in Microbiology and Immunology 158:97-129</u>
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>
/David Guzo/		09/15/2008
<b>*EXAMINER:</b> Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		

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(REV. 8-83) Patent and Trademark Office

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	Kotin, R.M, "Prospects for the Use of Adeno-Associated Virus as a Vector for Human Gene Therapy," <u>Human Gene Therapy</u> 5:793-801 (1994)
	Emerman, M et al., "Genes with Promoters in Retrovirus Vectors Can Be Independently Suppressed by an Epigenetic Mechanism," <u>Cell</u> 39:459-467 (1984)
	Emerman, M et al., "Quantitative Analysis of Gene Suppression in Integrated Retrovirus Vectors," <u>Molecular and Cellular Biology</u> 6(1):792-800 (1986)
	Yu, S.F et al., "Self-inactivating retroviral vectors designed for transfer of whole genes into mammalian cells," <u>Proc. Natl. Acad. Sci. USA</u> 83:3194-3198 (1986)
	Hawley, R.G. et al., "Handicapped retroviral vectors efficiently transduce foreign genes into hematopoietic stem cells," <u>Proc. Natl. Acad. Sci. USA</u> 84: 2406-2410 (1987)
	Yee, J.K et al., "Gene expression from transcriptionally disabled retroviral vectors," <u>Proc. Natl. Acad. Sci. USA</u> 84:5197-5201 (1987)
EXAMINER	DATE CONSIDERED
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Form PTO-1449 U.S. Department of Commerce (REV. 8-83) Patent and Trademark Office  INFORMATION DISCLOSURE CITATION (use several sheets if necessary)	Atty. Docket No. ENZ-56(D3)	Serial No. 09/046,840
	Applicants: Dakai Liu and Elazar Rabbani et al.	
	Filed: March 24, 1998	Group: 1636

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DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN- SLATION YES NO

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Dougherty, J.P and Temin H.M., "A promoterless retroviral vector indicates that there are sequences in U3 required for 3' RNA processing," <u>Proc. Natl. Acad. Sci. USA</u> 84:1197-1201 (1987)	11 12
	Whitcomb, J.M and Hughes, S.H., "Retroviral Reverse Transcription and integration: Progress and Problems" <u>Ann. Rev. Cell Biol.</u> 8:275-306 (1992)	
	Jaenisch, R et al., "Germline Integration of Moloney Murine Leukemia Virus at the Mov13 Locus Leads to Recessive Lethal Mutation and Early Embryonic Death," <u>Cell</u> 32:209-216 (1983)	
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Applicants: Dakai Liu and Elazar Rabbani et al.		
Filed: March 24, 1998		Group: 1636



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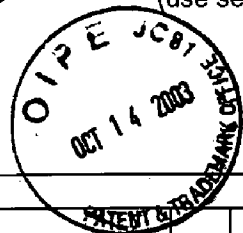
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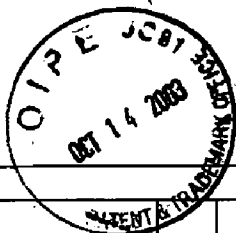
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